

Atty. Dkt. WEG-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Edwin Wegman, et al.
Serial No. : 08/356,112
Examiner : Ms. Jean C. Witz
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GAU : 1808
For : Reduction of Adipose Tissue

DECLARATION

I, Edwin Wegman, declare that:

I am President of Advance Biofactures Corporation of Curacao, NV, assignee of the above-identified patent application. I have been engaged in chemical and pharmaceutical research for 30 years.

The following experiments were conducted under my supervision and direction in the laboratories of Advance Biofactures Corporation in Lynbrook, New York.

In a series of experiments it was shown that injection of solutions of collagenase in saline into fat pads of Zucker rats caused the digestion of the fat pads (adipose tissue), and that injection of saline alone in the same amount and in the same way in a control fat pad in the same rat caused no disruption and had no other effect on the control fat pads.

In order to quantify the extent of reduction of the amount of adipose tissue, the following experiment was carried out.

Number of rats: One Zucker

Test solution: 1,000 ABC units collagenase in 0.5 mL saline

Method: 0.5 mL of the test solution containing 1,000 units was injected percutaneous in 0.1 mL increments into three fat pads. The fourth pad was injected with 0.5 mL control saline.

Results: The rat was sacrificed, and the fat pads were dissected out and weighed. The control pad showed no reduction in size or different appearance from normal.

Control site upper left -- 12.1 grams

Test site upper right -- 7.1 grams

Test site lower right -- 9.1 grams

Test site lower left -- 9.9 grams

Summary/
Observations:

At this dosage, the fat pads lost, respectively, 41%, 25% and 18% of the weight of the control pad; average loss was 28%.

Based on a one side "T" test there was a significant statistical difference between the control and the test sites.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and any patent issuing thereon.

11/4/96
Date


Edwin Wegman